6304. Trim Reducing-Aid cigarettes. (F.D.C. No. 42216. S. No. 34-778 P.)

QUANTITY: 354 bulk ctns., each containing 1 display ctn. containing 10 retail pkgs., 20 cigarettes each, at Trenton, N.J.

SHIPPED: Between 3-24-58 and 7-11-58, from New York, N.Y., by Cornell Drug Corp.

LABEL IN PART: (Bulk ctn.) "TRIM Reducing-Aid Cigarettes" and (retail pkg.) "TRIM Reducing-Aid Cigarettes Filter Tip—20 Active ingredients: Combustible tartaric acid, combined with tobacco and flavoring."

Accompanying Labeling: Window display streamers reading in part "OVER-WEIGHT * * * Smoke Trim Reducing-Aid Cigarettes" and catalog sheets reading in part "Mr. Retailer How To Get Your Share."

LIBELED: 10-6-58, Dist. N.J.

CHARGE: 502(a)—when shipped and while held for sale, the labeling of the article contained statements which, when considered and interpreted in the setting in which they were presented, represented and suggested that smoking three Trim cigarettes per day would bring about a definite weight loss over a given period of time: that Trim cigarettes were safe for use by all persons; that use of Trim cigarettes would enable one to lose weight without dieting; that the user of Trim cigarettes could continue to eat the same kinds and amounts of food he ordinarily consumed and still lose weight; that Trim cigarettes were a new, scientific discovery approved by doctors and other scientists; that Trim cigarettes were marketed only after being subjected to years of clinical tests by doctors and other scientists; and that Trim cigarettes were the miracle reducing discovery of the century, which statements were false and misleading since they were contrary to fact; 502(b)(1)—the article failed to bear a label containing the place of business of the manufacturer, packer, or distributor; and 505(a)—the article was a new drug which may not be introduced into interstate commerce since an application filed pursuant to the law was not effective with respect to the drug.

Disposition: On 12-20-58, Cornell Drug Corp., appeared as claimant and filed an answer denying that the article was misbranded and that the article was a new drug. Thereafter, the Government filed written interrogatories and upon the claimants failing to answer, the Government filed a motion for a default decree of condemnation. The claimant filed motions to dismiss similar libel proceedings against the article pending in the United States District Courts for Dist. Kans., S. Dist. Calif., and N. Dist. Ohio, and for an order consolidating the proceedings and their removal for trial to the United States District Court for the E. Dist. N.Y.

On 6-15-59, the court denied the motions of the claimant and the Government, and further ordered that the motion for consolidation be denied on condition that the Government hold in abeyance, proceedings on all similar seizures in other jurisdictions pending the decision in the Dist. N.J. Thereafter, the claimant filed written interrogatories against the Government. The Government subsequently filed a motion to compel the claimant to make further and more complete answers to the previously served interrogatories, and objections to the claimants interrogatories, and a motion for protective order. The claimant filed a motion for a partial summary judgment striking out the new drug charge of the libel. Thereafter, the Government filed a motion for summary judgment. After a hearing on the motion for summary judgment the court, on 11-30-59, handed down the following opinion:

Wortendyke, District Judge: "Pursuant to Section 304 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 334) the Government filed a libel of information praying seizure and condemnation of what is thereon alleged to be an article of drug, shipped in interstate commerce by Cornell Drug Corporation, of 71 West 23rd Street, New York City, and 5 Davis Street, Cambridge, Massachusetts, consisting of 354 bulk cartons, more or less, containing retail packages of an article labeled "Trim Reducing-Aid Cigarettes." Acting in compliance with a warrant of seizure and monition, the United States Marshal for the District of New Jersey seized the articles listed in the libel which were, at the time of seizure, in the possession of Trenton Tobacco Company at the City of Trenton, in the District of New Jersey.

"Cornell Drug Corporation claimed the articles seized as owner thereof, and admits in its answer that the articles had been shipped by claimant to New Jersey in interstate commerce, for purposes of sale. After discovery proceedings had been availed of by the parties, claimant noticed a motion, returnable September 14, 1959, and thereafter from time to time adjourned, for an order "for partial summary judgment * * * striking out Paragraph designated "5" of the libel of information.' The paragraph of the libel referred to in the notice of that motion alleged that the Trim Reducing-Aid cigarettes was a New Drug, as defined in 21 U.S.C. § 321(p) (1), for which an application was required to be filed by §355(a) of that Title, and that such an application with respect to the article seized in these proceedings was not effective as required by subsection (b) of the latter section. Before the argument on claimant's said motion, libelant moved for summary judgment for the relief prayed for in the libel, basing its motion upon the pleadings, and moving affidavits and upon claimant's answers to libelant's interrogatories. Both of these motions were heard and have been considered together.

"Upon its motion libelant contends that the articles seized consisted of a drug shipped in interstate commerce, misbranded in violation of 21 U.S.C. § 334(a), when introduced therein, and constituting a new drug with respect to which an effective new drug application was not on file, as required by 21 U.S.C. § 355(a). In support of said motion there are submitted the respective affidavits of four physicians and two other individuals dealing with the question whether volatilized tartaric acid of the product of pyrolysis of tartaric acid is generally recognized as safe for human inhalation. It is the expressed opinion of each of these expert medical deponents, and by each of them stated to be the consensus of informed medical and scientific opinion,

that tartaric acid in cigarettes is not safe for use in cases of obesity.

"In support of claimant's motion to strike the aforementioned 'new drug' allegations from the libel, there were submitted affidavits, respectively of claimant's president, Murry Abbott, copies of letters to claimant from a drug manufacturer and from a tobacco manufacturer, as well as affidavits of two Doctors of Medicine and one Bachelor of Science in Chemistry. From these documents it appears that Trim cigarettes are composed of tobacco to which is added, as a flavoring, a substance or substances, including tartaric acid. among the components thereof. Each of the claimant's medical deponents expresses the opinion that Trim cigarettes are safe for use by human beings, as prescribed by claimant, and the affidavit of the Chemist states that to the best of his knowledge the amount of tartaric acid found in Trim cigarettes is absolutely harmless.

"The subject of these condemnation proceedings is a quantity of cigarettes intended to be smoked by human beings for the purpose of achieving and represented by claimant to be effective for a reduction in weight of the body of the users. These cigarettes are offered for sale in packages of twenty. The exterior of each package bears a legend that the contents are 'trim reducing-aid cigarettes'; that the active ingredients of each of these cigarettes are 'combustible tartaric acid, combined with tobacco and flavoring.' Upon the back of each package are directions for the use of the contents, viz: 'Smoke one cigarette shortly before meals . . . and whenever you are tempted to reach for a late evening snack. Trim reducing-aid cigarettes contain a patented appetite satient that takes the edge off your appetite. Clinically tested . . . Trim reducing-aid cigarettes are "GUARANTEED" to satisfy you or your money back.' The exterior of the package further discloses that the contents are manufactured for Cornell Drug Corp., United States Patent No. 2,773,785. Two panels of the display card of Trim ciga-

rettes seized in this action advertise that the cigarettes sell for Two Dollars per pack, plus tax, and inform intending purchasers that these reducing-aid cigarettes are not intended to replace the purchaser's favorite cigarettes nor to change his present smoking habits. The notice further suggests that the user smoke three or four reducing-aid cigarettes a day, that the article has been clinically tested, that satisfaction is guaranteed, and that the cigarettes consist of a scientific blend of finest quality tobacco. A window display streamer, to be employed for purposes of retail marketing of Trim cigarettes, which was also seized in this proceeding, is designed to attract the attention of a prospective purchaser by the following exhortative language. 'OVER-WEIGHT? Lose weight without pills or diet. Smoke Trim reducing-aid cigarettes. Absolutely harmless. Five years of successful clinical tests. A full week's supply in one package. Smoke three a day. Patented by United States Government. Enjoy along with your favorite cigarettes—as advertised on T.V.!' Salesmen's catalogue sheet, also seized with the articles here proceeded against, addresses the retailer as follows: 'Mr. Retailer out to get your share of a . . . \$500,000,000 market,' and then presents, over the name Cornell Drug Corp., 5 Davis St., Cambridge, Mass., printed and graphically illustrated information that Trim reducing-aid cigarettes are a scientifically proven reducing aid backed by a national advertising campaign with radio, T.V., magazine and newspaper saturation, point-of-sale merchandising, and window displays, and a statement that there is a full \$6.66 per carton profit for the retailer. The same circular reiterates the admonition to users 'Puff your pounds away, Smoke 3-4 a day,' gives assurance that by so doing pills and drugs are eliminated, represents that the product has been clinically tested, and announces that one package contains a week's supply, that the product is patented by United States Government, is scientifically blended and is backed by five years of successful clinical tests. Following the further admonition 'Watch your weight go up in smoke,' the retailer is assured that the product sells everywhere, on drug counters, in tobacco departments and in cosmetic departments.

"The claimant admits all of the foregoing representations, exhortations, suggestions and directions. In addition to the employment of the foregoing media and methods of advertising and sales inducements claimant admits that the following is typical of the text of its radio and television 'commercials': 'It's here . . . a great scientific discovery . . . TRIM, reducing-aid cigarettes that curb your appetite. Imagine . . . now you can lose up to twenty pounds or more, simply by smoking this delightful tasting cigarette . . . without giving up your favorite brand. Just light up a TRIM reducing-aid cigarette before each meal. Watch your weight go up in smoke. TRIM cigarettes contain a patented ingredient that stops that urge to eat fattening foods with your first puff. It's "will-power" in tobacco form. TRIM cigarettes have been clinically tested and medically approved . . . The results are excellent. Patients have lost up to twenty pounds or more in eight weeks . . . the safe, simple way. Puff your pounds away with TRIM cigarettes. Watch your weight go down, down! Harmless, non-habit forming. Light a TRIM cigarette at night, when you're tempted to raid the ice box . . . they work instantly. Appease your appetite. Even non-smokers can reduce with TRIMs. You smoke only three a day. TRIM reducing-aid cigarettes make reducing fun. Get your first pack of TRIM cigarettes today at drug counters. Safely lose up to twenty pounds or double your money back.'

"There is attached to claimant's answers to interrogatories a copy of United States Patent No. 2,773,785 issued December 11, 1956, to Edgar A. Ferguson, Jr., of Brooklyn, New York. One of the five claims of said patent reads as follows: '1. As a new article of manufacture a combustible substance adapted to be used in smoking having intimately admixed therewith and distributed therethrough tartaric acid in an amount of between 0.01–0.04 gram tartaric acid per each gram of said combustible substance which upon combustion of said combustible substance volatilizes to act in the mouth of the person smoking to reduce the appetite.' Another claim of the patent substitutes the word 'tobacco' for the words 'combustible substance' in the foregoing, and the fourth and fifth claims refer to 'a cigarette adapted upon smoking to cause reduction of appetite having intimately admixed with the tobacco thereof and distributed therethrough tartaric acid' in certain specified

proportions. In this connection it is interesting to note that the title of this patent is 'Appetite Satient Composition' and describes the invention as relating to 'a new and improved therapeutic appetite satient composition designed to curb the appetite without supplying calories to the body and more particularly * * * a therapeutic appetite satient composition in combustible form

which can be smoked and upon smoking causes loss of appetite.'

"Among its answers to interrogatories is an admission by claimant that the patented appetite satient referred to in its labelling is combustible tartaric acid in the proportions therein disclosed, but claimant denies that chemical analyses have been made of unburned Trim cigarettes and states that it is ignorant of the chemical formula of the combustible tartaric acid used in the cigarettes. Claimant epitomizes its contentions respecting the efficacy of its product in the statement that use of these cigarettes in accordance with its directions curbs the appetite and in consequence discourages food ingestion and thereby induces loss of weight. In support of these contentions claimant asserts that it relies upon medical opinions furnished to it by certain New York physicians. With regard to the physiological effects upon human beings of the inhalation or ingestion of the combustion products of any form of tartaric acid, claimant points out that tartaric acid is used in baking bread. in which process it volatilizes and causes bakery workers to inhale the fumes without apparent adverse effects. With respect to the text of the Trim cigarette radio and television commercials, claimant admits the language used therein, but insists that the phraseology consists of metaphors or figures of speech, not to be taken literally. Nothing in the language employed is even remotely suggestive that it is not to be accepted as unqualifiedly true.

"The cross-motions pending before me present the following questions:

(1) Is the Trim reducing-aid eigarette, which was concededly shipped by claimant in interstate commerce and held for sale after such shipment, a drug as defined by 21 U.S.C. § 321(g) (3)?

(2) If the seized article is a drug, is it misbranded by misleading labelling

within the meaning of subsection (m) of the same section?

(3) Is the article sought to be condemned a new drug as defined in section

321(p)(1) of said Title?

(4) Was there, at the time of the introduction of the article into interstate commerce, an effective application on file with respect to such drug, as required by section 355(a) of Title 21?

"None of the foregoing questions requires the resolution of any genuine issue of a material fact in view of the results of the discovery process and the content of the affidavits submitted upon the respective pending cross-motions for summary judgment. This Court's jurisdiction is obvious, arising as it does under the provisions of the Act already referred to, and with the claimant's concession that the articles which have been seized were introduced by claimant into interstate commerce and held for sale after shipment therein. The motions for summary judgment are, therefore, appropriately brought under Rule 56 of the Federal Rules of Civil Procedure, without any complication through the persistence of a genuine issue of material fact. See *United States* v. 20 Cases, etc. Buitoni 20% Protein Spaghetti, D.C. Del. 1955, 130 F. Supp. 715, affd. per cur. 3 Cir. 1956. 228 F. 2d 912.

"The statute, 21 U.S.C. § 321(g), defines 'drug,' as the term is used in the Act, as '(3) articles (other than food) intended to affect the structure or any function of the body of man * * *; and * * * (4) articles intended for use as a component of any article specified in clause * * * (3); * * *.' The Trim cigarette involved in this litigation is obviously an article intended to affect the structure and/or function of the human body and contains, as a component, tartaric acid which affects the structure and/or functions of the body. Claimant readily concedes that its product is intended to affect the structure and functions of the human body by reducing the appetite for the ingestion of food and thereby achieving a reduction in the body's weight. The component of the cigarette which the claimant asserts is critically effectual in satiating the appetite is tartaric acid, which is used and intended by the claimant to be used in the composition of its cigarette.

"In United States v. 46 Cartons more or less, containing Fairfax Cigarettes, D.C.N.J. 1953, 113 F. Supp. 336, Judge Meaney of this Court held that cigarettes which were shipped in interstate commerce with leaflets suggesting that the cigarettes were effective in preventing respiratory and other diseases, came within the term 'drug' as used in the Act, and were accordingly subject to seizure for misbranding. Judge Meaney's language, at page 338, is particularly apposite to the case before us: 'If claimant's labelling was such that it created in the mind of the public the idea that these cigarettes could be used for the mitigation or prevention of the various named diseases, claimant cannot now be heard to say that it is selling only cigarettes and not drugs.' To contend that the claimant's labelling in the case at bar would not create in the mind of a weight-conscious potential purchaser the idea that Trim cigarettes could be used for reducing his or her weight, is to speak with tongue in cheek, if not to display a most extraordinary naivete. In Bradley v. United States, 5 Cir. 1920, 264 Fed. 79, cited in the Fairfax case, supra, mineral water was shipped in interstate commerce labelled as recommended in the treatment of Bright's disease. The court in that case stated that when false and fraudulent representations are made with respect to the curative effect of water 'it would be trifling to say that water ordinarily is not a drug in the true meaning of the word, and therefore does not fall within the con-demnation of * * * the Act.' The seized articles in the present case are drugs within the meaning of the Act.

"The Government charges that the seized articles are misbranded because their labelling is misleading. The Act defines 'label' as 'a display of written, printed or graphic matter upon the immediate container of any article': 21 U.S.C. § 321(k), and subdivision (m) of the same section defines 'labeling' as meaning 'all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.' The succeeding subdivision of that section (n) provides that 'in determining whether the labelling is misleading there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, or any combination thereof, but also the extent to which the labelling fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the article to which the labelling relates under the conditions of use prescribed in the labelling thereof or under such conditions of use as are customary or usual.' Not only does claimant concede that the labels on the immediate containers of its cigarettes were inducive of use of its product for the purpose of weight reduction, but an inspection of the copies of the panels of the display cartons of the cigarettes, the window display streamer and the salesmen's catalogue sheet relating thereto clearly discloses that the primary, if not the sole inducement intended by the claimant to the purchase and use of its product was the representation of the product's efficacy to reduce human avoirdupois. See Kordel v. United States, 1948, 335 U.S. 345; and 62 cases of Jam v. United States, 1951, 340 U.S. 593. Upon the uncontested evidence in this case, I cannot avoid the conclusion that the accused articles are misbranded because the labels upon their containers and accompanying the articles are misleading, if not actually false and fraudulent. See United States v. 353 Cases etc. Mountain Valley Mineral Water, 8 Cir. 1957, 247 F.

"Libelant contends that the seized articles are a new drug. Claimant contends to the contrary, and upon their respective contentions each party has moved for summary judgment. The statute, 21 U.S.C. § 321(p) (1) defines a new drug as 'any drug the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety of drugs, as safe for use under the conditions prescribed, recommended, or suggested in the labelling thereof, * * *.' Having determined that the seized articles are a drug, we look to the record upon which the pending cross-motions depend to ascertain whether 'such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety of drugs, as safe for use under the conditions prescribed, recommended, or suggested in the labelling thereof.' It has already been found and concluded that the Trim cigarette is a drug, which claimant recommends and suggests, in the labelling thereof, for use for the

purpose of human body weight reduction. That use necessarily involves the combustion of the tobacco and the other ingredients in the cigarette by smoking, and thereby bringing into contact with the membranes in the person's oral cavity, if not in his throat and/or lungs, the combustion products of the appetite satient tartaric acid, which is not only concededly an ingredient of claimant's product, but intended by the claimant to have the effect for which its use is recommended. Is the Trim cigarette laden with the ingredient appetite satient and intended to become effective through smoking and the contact of the products of such combustion with the membranes of the oral cavity, generally recognized as safe for use under such conditions? It is obvious that there is disclosed in the supporting affidavits a direct contrariety of medical and scientific opinion respecting the answer to this question. The existence of such a conflict of expert opinion does not create a genuine issue of material fact obstructive of the motions here confronting us. that each of the deponents is duly qualified to express an opinion respecting the safety of the drug for the purposes recommended by claimant, the genuine difference of opinion among the medical experts disclosed by the affidavits, indicating lack of the 'general recognition' required, brings the seized articles clearly within the statutory definition of a new drug. The Merritt Corp. v. Folsom, Secretary, etc., D.C. D.C. 1958, 165 F. Supp. 418. In the cited case the Court was confronted with the question whether topical neomycin sulfate was safe for treatment of acne. The evidence disclosed a genuine difference of opinion among medical experts respecting the safety of the particular drug for the treatment of the particular disease. The Court concluded that because of this difference of opinion, it could not be concluded that the drug was generally recognized as safe for the use in the treatment of acne. Since, therefore, we have a similar genuine difference of opinion among experts qualified by scientific training and experience to evaluate the safety of drugs, as to the product here under consideration, that product becomes a new drug by the very terms of the statutory definition, i.e., because it does not appear that it is generally recognized as safe for the purposes for which the claimant recommends it.

"Respecting the requirement of 21 U.S.C. § 355(a) that no person shall introduce into interstate commerce any new drug unless an application filed pursuant to subsection (b) of that section is effective with respect to such drug, claimant's president admits in his affidavit that no such application was filed before the commencement of the sale of Trim cigarettes. He would, however, explain such failure to file such an application by the statement that it was orally excused, by telephone, by Dr. Ralph G. Smith, of the Medical Division of the Federal Food and Drug Administration. Abbott says that before the execution of the contract between claimant and Riggio Tobacco Corporation, for the manufacture by the latter of Trim cigarettes, counsel for the manufacturer insisted that the Administration be contacted for the purpose of ascertaining whether there was anything dangerous to human beings in their proposed ingredients. It appears that on December 12, 1957, in a telephone call to Mr. Harold O'Keefe, of the Administration, by claimant's attorney, the proposed use of a flavoring ingredient, 'coumarin,' in the formula at that time was disapproved and 'vanillin U.S.P.' was suggested by O'Keefe as a substitute for the disapproved coumarin. O'Keefe then requested that the same facts which had been presented to him be also presented to Dr. Smith for his medical opinion as to whether or not there was anything dangerous in the ingredients of Trim cigarettes. Abbott's affidavit states that Dr. Smith advised that it was unnecessary for a new drug application to be filed since the ingredients of the cigarette disclosed to him were all well-known and harmless for human use in the form prescribed. The amount of tartaric acid in the formula which Abbott sets forth in his affidavit is 0.0005 gram per cigarette. I shall assume that this formula was disclosed in the telephone conversation referred to, to Dr. Smith. In his affidavit, Dr. Smith admits that his business diary reveals his receipt of a telephone call from claimant's attorney, on the date mentioned by Abbott, with reference to a cigarette containing flavoring and tartaric acid, but that this diary 'does not reveal' that he advised the attorney that a new drug application would be unnecessary for the product, but the doctor expresses

the opinion that the use of tartaric acid in cigarettes is not generally recognized among experts qualified to evaluate the safety of drugs, as safe for use in a recurring condition such as obesity. Assuming that Dr. Smith, a Government employee, told claimant's attorney that it would be unnecessary for claimant to file a new drug application with the Administration, claimant's failure to comply with the statute in that regard cannot be excused under the theory of estoppel against the Government. See Wilber National Bank v. United States, 1935, 294 U.S. 120.

"For the reasons expressed in the foregoing opinion, I conclude that libelant's motion for summary judgment should prevail. An appropriate order

may be presented accordingly."

On 12-21-59, an order was entered in accordance with the above opinion granting summary judgment in favor of the Government and ordering that the article be condemned and destroyed.

G305. Trim Reducing-Aid cigarettes. (F.D.C. No. 42220. S. No. 23-656P.)
QUANTITY: 47 shipping cases, each containing 30 bulk ctns., of which each contained 1 display ctn. containing 10 retail packages, at Glendale, Calif.

SHIPPED: 9-9-58, by Cornell Drug Corp., New York, N.Y.

LABEL IN PART: (Pkg.) "TRIM Reducing-Aid Cigarettes Filter Tip—20 Active ingredients: Combustible tartaric acid, combined with tobacco and flavoring. Directions for use: Smoke one cigarette shortly before meals . . . and whenever you are tempted to reach for a late evening snack * * * contain a patented appetite satient that takes the edge off your appetite * * * Cornell Drug Corp."; (display ctn.) "NEW TRIM Reducing-Aid Cigarettes * * * Smoke 3 or 4 a day CURBS YOUR APPETITE * * * Clinically tested, Satisfaction guaranteed. A scientific blend of finest quality tobaccos U.S.A. Patent No. 2,773,785 * * * Not intended to replace your favorite cigarettenor to change your present smoking habits."

Accompanying Labeling: Pamphlets entitled "Mr. Retailer How to Get Your Share of a * * * \$500,000,000 Market."

LIBELED: 10-15-58, S. Dist. Calif.

CHARGE: 502(a)—when shipped and while held for sale, the labeling of the article contained false and misleading representations that smoking three Trim cigarettes per day would bring about a definite weight loss over a given period of time; that Trim cigarettes were safe for use by all persons; that use of Trim cigarettes enabled one to lose weight without dieting; that the user of Trim cigarettes could continue to eat the same kinds and amounts of food he ordinarily consumed and still lose weight; that Trim cigarettes were a new, scientific discovery approved by doctors and other scientists; that Trim cigarettes were marketed only after being subjected to years of clinical tests by doctors and other scientists; and that Trim cigarettes were the miracle reducing discovery of the century; 502(b) (1)—the article failed to bear a label containing the place of business of the manufacturer, packer, or distributor; and 505(a)—the article was a new drug which may not be introduced into interstate commerce since an application filed pursuant to law was not effective with respect to the drug.

DISPOSITION: Cornell Drug Corp., filed a claim and answer to the libel. Thereafter, various motions were made and proceedings occurred as set forth below in the following findings of fact, conclusions of law, and summary judgment entered by the court on 1-11-60: